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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 1699
This document relates to	CASE NO. 3:07-cv-5704-CRB
DANIEL SILVER, et. al., Plaintiffs, vs. PFIZER, INC., PHARMACIA CORPORATION, and G.D. SEARLE, LLC, Defendants.	**PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE, LLC'S ANSWER TO COMPLAINT** **JURY DEMAND ENDORSED HEREIN**

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC (improperly captioned in Plaintiffs' Complaint as "G.D. Searle, LLC") ("Searle") (collectively "Defendants"), and file this Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiffs were prescribed and used Bextra®.

II.

ANSWER

Response to Allegations Regarding Parties

1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

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2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States, including the States of California, Ohio, South Carolina, Florida, Illinois, Washington, Michigan, Arizona, Texas, and Maryland, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Bextra® in the United States, including the States of California, Ohio, South Carolina, Florida, Illinois, Washington, Michigan, Arizona, Texas, and Maryland, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore,

deny the same. Defendants deny the remaining allegations in this Paragraph of the Complaint.

Response to Allegations Regarding Jurisdiction and Venue

6. Defendants are without knowledge or information to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny that the same. However, Defendants admit that Plaintiffs claim that the amount in controversy exceeds $75,000, exclusive of interests and costs.

7. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship, and, therefore, deny the same. However, Defendants admit that Plaintiffs claim that the parties are diverse. Defendants deny the remaining allegations in this paragraph of the Complaint.

8. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny committing a tort in the States of California, Ohio, South Carolina, Florida, Illinois, Washington, Michigan, Arizona, Texas, and Maryland, and deny the remaining allegations in this paragraph of the Complaint.

9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States, including the States of California, Ohio, South Carolina, Florida, Illinois, Washington, Michigan, Arizona, Texas, and Maryland, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants admit that they do business in the State of Texas. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and,

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therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Interdistrict Assignment

10. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac. and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial Panel on Multidistrict Litigation on September 6, 2005.

Response to Factual Allegations

11. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

12. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this

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paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

17. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

18. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

19. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's citizenship, medical condition, and whether Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

20. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the

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same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

21. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

22. Defendants admit that Bextra® was expected to reach consumers without substantial change from the time of sale. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations this paragraph of the Complaint.

23. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny remaining the allegations in this paragraph of the Complaint.

24. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the

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same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

25. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

26. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDS"). Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

27. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

28. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

29. Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth

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of such allegations and, therefore, deny the same.

30. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

31. Plaintiffs do not allege having used Celebrex® in this Complaint. Nevertheless, Defendants admit that Celebrex® was launched in the United States in February 1999. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

32. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of

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such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

33. Defendants admit that Bextra® was approved by the FDA on November 16, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

34. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

36. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be

prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

37. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

39. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this paragraph of the Complaint.

40. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

41. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

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42. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to characterize the Talk Paper is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

43. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

44. Plaintiffs fail to provide the proper context for the allegations concerning the "post-drug approval meta-analysis study" in this paragraph of the Complaint. Defendants are without sufficient information to confirm or deny such allegations and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

45. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

46. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

47. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

48. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.

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Defendants deny the remaining allegations in this paragraph of the Complaint.

49. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

51. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

52. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

54. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

56. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

57. The allegations in this paragraph of the Complaint are not directed towards Defendants

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and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

58. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

59. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

60. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

61. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and

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effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the allegations in this paragraph of the Complaint.

62. The allegations in this paragraph of the Complaint regarding Vioxx® are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Vioxx®. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

63. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

64. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

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applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

65. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

66. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications ("DDMAC") sent a letter to Pfizer dated January 10, 2005. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants admit that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

67. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that the referenced press release speaks for itself and respectfully refer the Court to the press release for its actual language and text. Any attempt to characterize the press release is denied. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied.

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Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

68. Defendants state that the referenced press release speaks for itself and respectfully refer the Court to the press release for its actual language and text. Any attempt to characterize the press release is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

69. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

70. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

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71. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

72. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

73. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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the Complaint.

75. Defendants deny the allegations in this paragraph of the Complaint.

76. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

77. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding and whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that the referenced press releases speak for themselves and respectfully refer the Court to the press releases for their actual language and text. Any attempt to characterize the press releases is denied. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

78. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding and whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

79. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

80. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

81. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance

with their approval by the FDA. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

83. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Negligence

84. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

85. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

86. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

87. Defendants state that this paragraph of the Complaint contains legal contentions to

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which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

88. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

90. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

91. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

92. The allegations in this paragraph of the Complaint regarding Vioxx® are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiffs fail to provide the proper context for the allegations in this paragraph of the Complaint regarding Vioxx®. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

93. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

94. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

95. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage and deny the remaining allegations in this paragraph of the Complaint.

96. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

97. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

98. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants admit that Bextra® was expected to reach consumers without substantial change in the condition from the time of sale. Defendants state that Bextra® was and is safe

and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

99. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

100. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

101. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

102. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its

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FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

103. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

104. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is defective and deny the remaining allegations in this paragraph of the Complaint.

105. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

106. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

107. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

108. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

109. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

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Defendants deny the remaining allegations in this paragraph of the Complaint.

110. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

111. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

112. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

113. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

114. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this

paragraph of the Complaint.

115. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

116. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

117. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Breach of Express Warranty

118. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

119. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

120. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint, including all subparts.

121. Defendants deny the allegations in this paragraph of the Complaint.

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122. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

123. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of the Complaint.

124. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

125. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

126. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

127. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or

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damage, and deny the remaining allegations in this paragraph of the Complaint.

128. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

129. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach of Implied Warranty

130. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

131. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

132. Defendants admit that they provided FDA-approved prescribing information regarding Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

133. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny

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the remaining allegations in this paragraph of the Complaint.

134. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

135. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was expected to reach consumers without substantial change in the condition from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

136. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

137. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

138. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

139. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

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140. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

141. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment

142. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

143. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is deemed required. To the extent a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

144. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

145. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

146. Defendants state that Bextra® was and is safe and effective when used in accordance

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with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

147. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

148. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

149. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

150. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

151. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

152. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

153. Defendants are without knowledge or information sufficient to form a belief as to the

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truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

154. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

155. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

156. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

157. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

158. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Unjust Enrichment

159. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

160. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are

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by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

161. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

162. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

163. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

164. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiffs used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

165. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

Answering the unnumbered paragraph of the Complaint headed "Prayer for Relief," Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiffs injury or damage, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

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III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the

applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiffs' action is barred by the statute of repose.

Seventh Defense

7. Plaintiffs' claims against Defendants are barred to the extent Plaintiffs were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs .

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiffs'

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treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiffs was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiffs' alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Nineteenth Defense

19. Plaintiffs knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by

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the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint was at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f

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to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of South Carolina, Florida, Arkansas, Mississippi, and California, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiffs failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

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Thirty-sixth Defense

36. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of South Carolina, Florida, Arkansas, Mississippi, and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs ; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any

punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

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Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiffs .

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Bextra® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of

responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs .

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs' misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered

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by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs' recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by Rule 1.120 of the Florida Rules of Civil Procedure.

Fifty-ninth Defense

59. Plaintiffs' claims are barred because Bextra® was designed, manufactured, and marketed in accordance with the state of the art at the time of manufacture per § 768.1257, Florida Statutes.

Sixtieth Defense

60. Bextra® is not defective or unreasonably dangerous, and Defendants are not liable because, at the time of sale or distribution of the Bextra® alleged to have been used by Plaintiff and Decedent, Defendants had complied with applicable regulations of the federal Food & Drug Administration and are entitled to application of § 768.1256, Florida Statutes.

Sixty-first Defense

61. Plaintiffs' and Decedent's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiffs and Decedent, or persons or parties whose identities are unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiffs' recovery. Thus, Defendants are entitled to have its liability to the Plaintiffs, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to the provisions of § 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to §§ 768.31 and 768.81, Florida Statutes, judgment must be entered on

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the basis of Defendants' percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendants will be identified in a timely manner consistent with *Nash v. Wells Fargo*, 678 So. 2d 1262 (Fla. 1996).

Sixty-second Defense

62. Plaintiffs fail to state a claim for violation of The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA").

Sixty-third Defense

63. FDUTPA does not apply to claims for personal injuries, and, accordingly, Plaintiffs' FDUTPA claim is improper and should be dismissed.

Sixty-fourth Defense

64. The acts or practices of which Plaintiffs complain were and are required or specifically permitted by federal or state law. Therefore, Plaintiffs' FDUTPA claim is barred, fails to state a claim, and should be dismissed with prejudice.

Sixty-fifth Defense

65. Plaintiffs lack standing because Defendants did not engage in deceptive conduct with regard to Plaintiffs or Decedent or otherwise.

Sixty-sixth Defense

66. Plaintiffs' claims are barred, in whole or in part, pursuant to South Carolina Code Ann. § 15-3-20.

Sixty-seventh Defense

67. Plaintiffs' fraud based claims, if any, are not stated with particularity as required by Rule 9 of the Arkansas Rules of Civil Procedure.

Sixty-eighth Defense

68. Plaintiffs' damages, if any, must be reduced by the percentage of fault attributable to Plaintiffs and Decedent and to nonparties as provided by Ark. Code Ann. § 16-55-202.

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Sixty-ninth Defense

69. Plaintiffs' claims are barred and/or limited by the provisions of the Arkansas Products Liability Act, Ark. Code Ann. § 16-116-101, et seq.

Seventieth Defense

70. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Arkansas Civil Justice Reform Act of 2003, Ark. Code Ann. § 16-55-201, et seq.

Seventy-first Defense

71. To the extent that Plaintiffs rely upon any theory of breach of warranty, Plaintiffs' claims are barred because Defendants did not make or breach any express or implied warranties, Plaintiffs and Decedent failed to give reasonable notice to Defendants of any alleged breach or breaches of warranty as required by Miss. Code Ann § 75-2-607(3)(a).

Seventy-second Defense

72. Any verdict or judgment rendered against Defendant must be reduced under the laws of the State of Mississippi by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiffs, such as insurance, social security, worker's compensation, or employee benefits programs. Plaintiffs and Decedent may have settled their claims for alleged injuries and damages with certain parties. Defendants therefore are, in any event, entitled to a credit in the amount of any such settlement heretofore made between Plaintiffs or Decedent and any such parties.

Seventy-third Defense

73. Plaintiffs' claims for punitive damages are limited or barred by the standards governing exemplary damage awards which arise under the United States Constitution and decisions of the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper* Industries*, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi Constitution, statutes, and decisions of Mississippi courts.

Seventy-fourth Defense

74. Defendant asserts that Plaintiffs' claim for punitive damages is governed and limited by

Miss. Code Ann. § 11-1-65, and Defendants hereby plead and invoke the provisions of the same.

Seventy-fifth Defense

75. Bextra® and the Defendants' actions conformed to the state of the art medical and scientific knowledge at all times relevant to this lawsuit and Bextra® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

Seventy-sixth Defense

76. Defendants satisfied their duty to warn under the learned intermediary doctrine and Plaintiffs' claims are therefore barred.

Seventy-seventh Defense

77. Defendants hereby plead all defenses contained in Miss. Code Ann. § 11-1-63 and hereby invoke the provisions of Miss. Code Ann. § 85-5-7.

Seventy-eighth Defense

78. Plaintiffs failed to join all indispensable parties; as a result of such failure to join, complete relief cannot be accorded to those already parties to the action and will result in prejudice to Defendant in any possible future litigation.

Seventy-ninth Defense

79. Any judicially-created definitions of manufacturing defect and design defect, and standards for determining whether there has been an actionable failure to ward, are unconstitutional in that, among other things, they are void for vagueness and undue burden on interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.

Eightieth Defense

80. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any award of punitive damages is barred.

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Eighty-first Defense

81. Plaintiffs' claims are barred in whole or in part because Plaintiffs lack standing to bring such claims.

Eighty-second Defense

82. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;

2. That the Complaint be dismissed;

3. That Defendants be awarded their costs for this lawsuit;

4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses or damages is attributable to each person;

5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and

6. That Defendants have such other and further relief as the Court deems appropriate.

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March 26, 2008

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

March 26, 2008

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